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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,085	KOSTER ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5, 6, 10, 15, 17, 18, 22, 25, 34, 38, 43, 44, 46, 47, 55, 56, 63, 66-68, 75, 77-79, 95-97, 99, 101, 102, 106, 107, 110, 116, 127, 128, 130-134, 137, 139, 140, 143-147, 150-153, 155-161, 163, 164, 166-173 drawn to a method comprising contacting a capture compound with a sample, classified variously in class 435, DIG 2.

II. Claim 81 drawn to a collection of capture compounds, classified variously in class 435, DIG 22.

III. Claim 82 drawn to a capture compounds, classified variously, in class 552, subclass 101, 105, etc. depending on the nature of the structure of the compound.

IV. Claims 118 and 120, drawn to a system for analysis of mixtures of biomolecules, classified variously, in class 435, DIG 45.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-IV represent separate and patentably distinct inventions. Groups I is drawn to a methods whereas Groups II-IV are drawn to different products and/or apparatus (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding

patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features.

4. However, if Applicants were to argue that Groups II-IV (individually) and I are related as product and process of use, respectively, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product of (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, (1) the process for using the product can be practiced with a materially different product (e.g., the product of Group II, III or IV). In addition, the product as claimed can be used in a materially different process of using the product (e.g., the product can be used as a starting materially to form more libraries, can be used as a therapeutic drug or a homing device, immunoassays and/or bioassays that do not involve an "isolation" step, etc.).

5. In addition, Groups II-IV represent patentably distinct products. Groups II and III represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group II is drawn to a library (i.e., a collection of compounds), whereas Group III is drawn to single compound. Different reagents and materials are required to produce a library and a library is also used for a different purpose than a single compound (e.g., an array is used for a library that

is not use for a single compound). In addition, Group IV requires a computer, mass spectrometer, etc. that are not required by Groups II and III. Therefore, art anticipating or rendering obvious each Group would not render obvious the other Group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups II-IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

8. If applicant elects the invention of Groups I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of capture compound (e.g., see claims 1, 10, 15, 22, etc.)

Applicant must elect for purposes of search a ***single species*** of capture compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said capture compound (e.g., see figures 23A-23D; see also figure 17 and 21 and claims 168 and 173 wherein Y is defined; see also claim 46 and figure 16 wherein X is defined; see

also claim 75 wherein Q is defined). Applicant should NOT use general notations like Q, Z, X, Y, m, n, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Applicants must further indicate whether Q permits separation of capture compounds by arraying of the capture compounds on a solid support (e.g., see claim 10). Applicants must further indicate whether said capture compound is cleavable and if so whether said compound cleavable during or prior to mass spectrometric analysis (e.g., see claim 15) and also whether said Z component in photocleavable, acid cleavable, etc. (e.g., see claim 25). Applicants must further indicate whether Q is an oligonucleotide (e.g., see claim 22). Applicants must further indicate and mass modifying tags linked to Z (e.g., see claim 46 and 47). Applicants must further indicate whether said capture compounds are hybridized to a plurality of complementary oligonucleotides or analogs thereof (e.g., see claim 55) and whether said complementary oligonucleotides are immobilized on a solid support such as an array (e.g., see claim 56). Applicant must also indicate whether said Z moiety confers luminescence, fluorescence, etc. (e.g., see claim 63). Applicants must further identify any solubility group W that is contained in the molecule (e.g., see claim 66). Applicants must further indicate whether X is a photoactivatable group and whether said capture compound interacts with the biomolecule mixture prior to activation of the photoactivatable group (e.g., see claims 139 and 140). Applicants must further indicate whether X is a latent reactivity group requiring activation following contacting with the biomolecule to allow for reaction with biomolecules (e.g., see claims 150 and 152).

Subgroup 2: Species of biomolecule (e.g., see claims 1, 2, 6, etc.)

Applicant must elect, for the purposes of search, a ***single species*** of biomolecule (e.g., see claim 6 wherein a protein is disclosed). Applicants must also indicate whether said biomolecule contains drug targets and non-targets (e.g., claim 2). Applicants must further indicate whether said biomolecule is a protein conformer (e.g., see claim 95) and if so whether or not it is associated with a disease (e.g., see claim 97). Applicants must also indicate a method for determining the function of the biomolecule e.g., sequence alignment (e.g., see claim 166).

Subgroup 3: Species of identification (e.g., see claims 1, 95, 96, 127)

Applicant must elect, for the purposes of search, a ***single species*** of identification e.g., mass spectrometry (e.g., see claim 96). Applicants must further indicate a specific type of identification e.g., MALDI (e.g., see claim 163). Applicants must also elect a format e.g., TOF (see claim 164). Applicants must also indicate whether said identification includes sorting cells from a single subject according to a predetermined phenotype method step (e.g., see claim 99) and if so further indicate the phenotype e.g., tumor (see claim 107).

Subgroup 4: Species of digestion if used (e.g., see claims 131)

Applicant must elect, for the purposes of search, a ***single species*** of digestion if used e.g., chemical (e.g., see claim 131).

Subgroup 5: Species of sample (e.g., see claim 116)

Applicant must elect, for the purposes of search, a ***single species*** of sample e.g., cell lysate (see claim 116).

Subgroup 6: Species of analysis (e.g., see claim 116)

Applicant must elect, for the purposes of search, a ***single species*** of analysis e.g., whether the method contains a method sep for contacting the capture compound-biomolecule complex with a mixture containing compounds selected from the group consisting of mixtures of biomolecules and small molecule test compounds. In addition, if said method of analysis does contain such a contacting step, Applicants must further elect a mixtures e.g., biomolecules, small molecules, etc. (e.g., see claim 116). In addition, Applicants must further specify the type of small molecule e.g., antibody (e.g., see claim 128) or the type of biomolecule e.g., protein (e.g., see claim 130).

Subgroup 7: Species of contacting (e.g., see claims 157 and 158)

Applicant must elect, for the purposes of search, a ***single species*** of contacting e.g., conditions whereby the interaction of the moiety Y with protein in sample reached equilibrium (e.g., see claim 157) or kinetically controlled (e.g., claim 170). Applicants must further indicate whether a covalent bond is formed by treatment (e.g., see claim 158). Applicants must further indicate whether said treatment involves a change in pH or an alteration in concentration of capture compounds (e.g., see claims 159 and 160) or the use of light (e.g., see claim 169).

Subgroup 8: Species of redesigning method if used (e.g., see claim 143)

Applicant must elect, for the purposes of search, a ***single species*** of redesigning method if used (see claim 143).

9. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 81 is generic.

Subgroup 1: Species of collection of capture compounds (see claim 81)

Applicant is required to elect, for purposes of a search, a single specific collection of compounds. The election should result in a ***particularly defined*** core structure that is shared by all collection members. In defining this core structure, all variable groups

should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a ***representative example*** of the collection must be elected.

10. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 82 is generic.

Subgroup 1: Species of capture compound (see claim 82)

Applicant must elect for purposes of search a ***single species*** of capture compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said capture compound (e.g., see figures 23A-23D; see also figure 17 and 21 wherein Y is defined; se also claim 46 and figure 16 wherein X is defined; see also claim 75 wherein Q is defined). Applicant should NOT use general notations like Q, Z, X, Y, m, n, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

11. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 118 is generic.

Subgroup 1: Species of collection of capture compounds (e.g., see claim 118)

Applicant is required to elect, for purposes of a search, a single specific collection of compounds. The election should result in a ***particularly defined*** core structure that is shared by all collection members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a ***representative example*** of the collection must be elected.

12. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 16 and 17 below).

13. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ.

Moreover, the above species can be separately classified. For example, the currently claimed capture compounds do not contain an art recognized common core structure that elicits a known common biological activity. Each part of the formula (e.g., Q, Z, X and Y) comprises molecular substituents with widely varying structure and function that can be separately classified (e.g., see claim 168 wherien celecoxib is used to treat arthritis pain whereas troglitazone, for example, is used to treat certain type of diabetes mellitus; also note that troglitazone contains a thiazolidine-2,4-dione whereas celecoxib is a nonsteroidal anti-inflammatory drug with a central pyrazole ring). Likewise the biomolecules have significantly different structure and function. Moreover, the species of isolation and detection vary in the method steps and equipment used (e.g., MALDI-TOF, electrospray etc.) Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

19. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

21. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
December 17, 2005

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5,6,10,15,17,18,22,25,34,38,43,44,46,47,55,56,63,66-68,75,77-79,81,82,95-97,99,101,102,106,107,110,116,118,120,127,128,130-134,137,139,140,143-147,150-153,155-161,163,164 and 166-173.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,6,10,15,17,18,22,25,34,38,43,44,46,47,55,56,63,66-68,75,77-79,81,82,95-97,99,101,102,106,107,110,116,118,120,127,128,130-134,137,139,140,143-147,150-153,155-161,163,164 and 166-173.